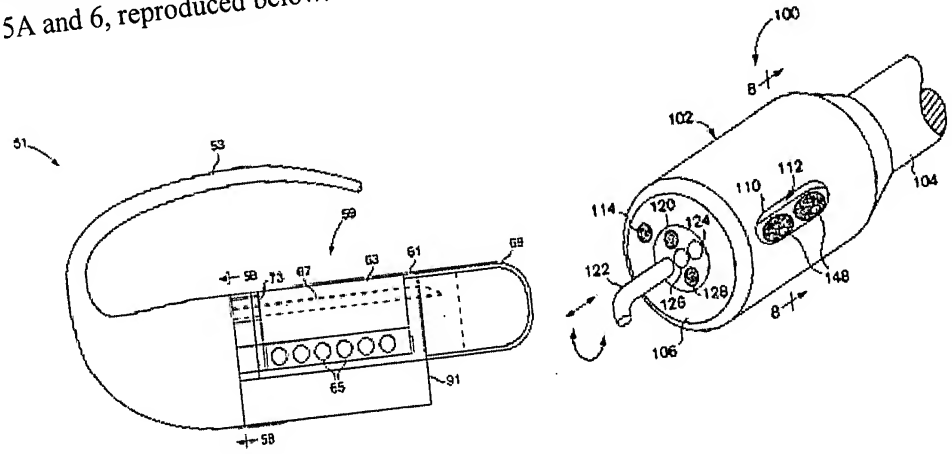
REMARKS

Claims 2-23 are currently pending in the application. Claim 1 was canceled in a previous paper. Claims 2 and 12 are amended. That the endoscope shaft has proximal and distal ends, and uninterrupted lumens extending through it, location of the accessory control elements within the endoscope shaft, and integration of the accessory housing into the distal end of the endoscope itself are disclosed in the specification at page 2, lines 17-21; from page 2, line 23 to page 3, line 26; page 11, line 30; page 12, lines 8-12; and is illustrated in FIGS. 5A and 6. No new matter is added.

THE INVENTION

Applicants' invention is a dedicated endoscope, that is, the endoscope and an operative treatment accessory are integrated and designed to operate together as a single structure, so as to avoid the problems common in systems where the treatment accessory is separate and removably attached to the distal end of the endoscope. The viewing capability of the endoscope is therefore not limited by the accessory itself, the accessory cannot become detached during use, and there is no incompatibility between the accessory and the endoscope, nor is there any difficulty in mounting the accessory controls on or in the endoscope.

That the treatment accessory and the endoscope are integrated into a single unit is shown in FIGS. 5A and 6, reproduced below:



The overall device includes an endoscope with a control mechanism for the accessory mounted at the proximal end of the endoscope, and an endoscope shaft with working channels and spaces specifically formed for the control elements and other necessary elements of the treatment accessory, such as cables, wires, or fluid or air pressure.

The endoscope includes a treatment accessory that includes a suction port capable of aspirating tissue into it, and a needle that is capable of sliding longitudinally through the accessory to penetrate tissue that has been aspirated into the suction port.

The treatment accessory can include a side suction port and a tissue capturing means that is advanced through the captured tissue along a circumferential path that rotates about the longitudinal axis of the endoscope. The suction port can also be partitioned so that the aspirated tissue is divided into two aspirated portions. The accessory can also have an angulated distal face oriented at an acute angle from the longitudinal axis of the endoscope, with the suction port located on the angulated distal face, and the needle configured to be advanced parallel to the distal face.

The invention also includes a method for performing an endoscopic medical procedure, by providing the endoscope as described above, navigating it to a treatment site within a patient, and performing the procedure without introducing a secondary medical device through the endoscope or external to the endoscope, and then withdrawing the endoscope from the patient.

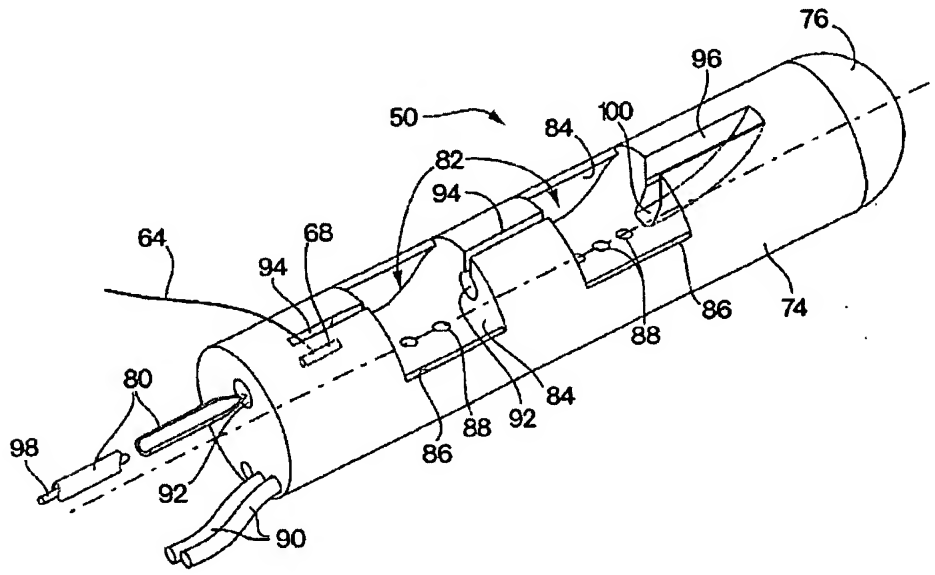
THE CITED ART

Gambale *et al.* (U.S. Pat. App. Pub. No. 2003/0208209; "Gambale")

U.S. Pat. App. Pub. No. 2003/0208209 to Gambale discloses an endoscopic tissue apposition device (50) (FIG. 6) with multiple suction ports (86), so that multiple folds of tissue can be captured with a single positioning of the device, and attached together by a tissue securement mechanism, such as a suture, staple, or other mechanism. The device is intended to minimize the number of intubations required in gastroplasty procedures. Prior devices required that the endoscope be removed after each stitch was made (paragraph 0009). The Gambale

device makes several stitches simultaneously, thus reducing the number of intubations required in the overall procedure.

The device is in the form of a capsule (FIG. 6) that can be attached to the distal end of an endoscope (paragraphs 0012, 0030, 0046, 0047, 0114, FIGS. 4, 5):



The capsule body can be injection-molded from a polymer material (paragraph 0017).

The vacuum channel of the capsule must also be joinable to the vacuum channel of the endoscope or independent vacuum line (paragraph 0117). In choosing the arrangement of the sutures in the tissue, consideration must be given to the arrangement of the suction ports in the capsule in relation to the working channels in the endoscope (paragraph 0014).

THE REJECTIONS

Claim Rejections Under 35 U.S.C. § 102(e)

Reconsideration is requested of the rejection of claims 2-23 as anticipated by the Gambale reference. The action misreads Gambale and incorrectly concludes that it discloses a treatment accessory that is integrated with an endoscope.

The Gambale reference discloses an apposition device (such as a sewing capsule) that is separate from, and attachable to, an endoscope. This concept appears throughout the text, for instance, at paragraph 0012 ("The device is comprised of a capsule *attachable to* the distal end of an endoscope"; emphasis added). Paragraphs 0030, 0046, 0047, 0114 ("Specifically, the device 140 is secured to the distal end of an endoscope and is navigated to a site of internal tissue intended to be sutured.") and 0158 also disclose that the capsule is mounted to the endoscope, as opposed that the two are permanently attached.

That the capsule is not permanently attached to the endoscope is also evidenced by other passages in the Gambale text. One such passage occurs in paragraph 0014: "In addition to the desired arrangement of tissue portions, consideration must be given to how securement means will be applied to the tissue portion given the arrangement of suction ports in relation to the working channel or channels of the endoscope." If the Gambale reference had intended that the capsule be integrated with the endoscope, it would not have been necessary to remind the reader to plan the arrangement of the suction ports of the sewing capsule with the working channel of the endoscope. This interpretation is confirmed at the end of paragraph 0117, which discloses that "[t]he air passages *[of the capsule]* are in communication with vacuum channel 234 formed through the capsule body and *joinable to* a vacuum channel 4 of the endoscope or an independent vacuum line." (emphasis added).

Paragraph 0017 discloses that previous capsule designs were assembled from several metal components, and that an advantage of the disclosed capsule is that the entire capsule body can be injection molded from a polymer material. There is no suggestion that the capsule body can be injection molded in combination with all or a part of the endoscope.

Gambale therefore fails to disclose that the endoscope and medical treatment accessory are integrated. Where Gambale fails to disclose integration of the two, it cannot be considered as anticipating any of applicant's claims, all of which include limitations, in varying degrees of specificity, to an integrated endoscope and medical treatment accessory.

Furthermore, the Gambale reference fails to disclose many aspects of the dependent claims. For instance, Gambale does not disclose a tissue apposition device that is formed as a cylindrical cartridge that mounts over a reduced diameter portion of the endoscope, as appears in FIG. 6 and claims 3 and 15 of the instant application. Gambale also does not disclose tissue capturing means that are advanced through the captured tissue along a circumferential path relative to the longitudinal axis of the endoscope (claims 4 and 16), nor does it disclose a semicircular needle (claims 6 and 18). The reference also does not disclose an angulated distal face oriented at an acute angle from the longitudinal axis of the endoscope, with the suction port located on the angulated distal face, and the needle configured to be advanced parallel to the distal face (claims 9 and 21). Nor does Gambale disclose a tissue grasping device arranged to be advanced through the access port to pull tissue through the port and into the accessory (claims 11 and 23).

Applicants therefore request that the rejection on the basis of this reference be withdrawn and reconsidered.

Applicant submits that all of the claims are now in condition for allowance, which action is requested. Please apply any charges or credits to Deposit Account No. 50-1721, Reference No.: 0506766.0137.

Respectfully submitted,

Joyce C. Hersh
Reg. No. 42,890
Attorney for Applicant
KIRKPATRICK & LOCKHART
PRESTON GATES ELLIS LLP
State Street Financial Center
One Lincoln Street
Boston, MA 02111-2950
Tel: 617-261-3100
Fax: 617-261-3175

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